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510(k) Summary
PosiSep™ and PosiSep™ X Hemostat Dressings

JUL 25 2012

Date Prepared: March 26, 2012 and revised July 9, 2012

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Proprietary Name: PosiSep™ and PosiSep™ X Hemostat Dressings

Common/Usual Name: Topical Hemostat

Classification Name: Topical Hemostat, Unclassified, Product Code FRO

Establishment Registration Number: 3007225047

Description:
The Hemostasis PosiSep™ and PosiSep™ X Hemostat Dressings are sterile hemostats comprised of modified Chitosan particles and polysaccharide binders. Chitosan has well known hemostasis properties and, when combined with carboxymethylcellulose and hydroxyethylcellulose binders, forms a foam-type dressing that has an affinity to absorb and hold water. PosiSep™ and PosiSep™ X Hemostat Dressings have the identical material composition as the currently market cleared Hemostasis ExcelArrest® Topical Hemostat. The PosiSep™ and PosiSep™ X Hemostat Dressings are used for topical wounds. The dressings quickly dehydrate blood cells, thereby causing rapid hemoconcentration of platelets, serum proteins and fibrinogen, leading to clotting that limits and controls bleeding and edema.

Indications for Use:
PosiSep™ and PosiSep™ X Hemostat Dressings are topical dressings for the temporary treatment of bleeding wounds such as surgical wounds (post operative, donor sites, dermatological), cuts and lacerations and for the treatment of mild bleeding from topical ENT surgical wounds and nosebleeds. PosiSep™ and PosiSep™ X are intended for use under the direction of a licensed healthcare provider.

Substantial Equivalence:
The PosiSep™ and PosiSep™ X Hemostat Dressings are substantially equivalent to the following predicate devices:

- Hemostasis ExcelArrest® Foam K072900
- Hemostasis NexFoam® Topical Hemostat K102459
- HemCon Bandage K043050/K072486

Biocompatibility:
Biocompatibility testing was performed using ISO 10993 – Biological Evaluation of Medical Devices and FDA guidance document Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices May 1, 1995 (G95-1). The PosiSep™ and PosiSep™ X Hemostat Dressings pass the biocompatibility requirements for their intended use.

Sterilization:
The PosiSep™ and PosiSep™ X Hemostat Dressings are sterilized using a validated gamma radiation method to assure a sterility assurance level (SAL) of 10^{-6}.

Performance Bench Testing:
Design verification testing was performed for the PosiSep™ and PosiSep™ X Hemostat Dressings to demonstrate physical and functional requirements were met.

Conclusion:
Through the data and information presented, Hemostasis, LLC considers the PosiSep™ and PosiSep™ X Hemostat Dressings substantially equivalent to the predicate devices already on the market (cleared by the 510(k) process) in terms of indications for use, scientific technology, design and functional performance and present no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 25 2012

Hemostasis, LLC
% Mr. Bernard Horwath
Hemastosis, Regulatory Affairs
5000 Township Parkway
Saint Paul, Minnesota 55110

Re: K120958
Trade/Device Name: PosiSep™ and PosiSep™ X Hermostat Dressings
Regulatory Class: Unclassified
Product Code: FRO
Dated: July11, 2011
Received: July 12, 2011

Dear Mr. Horwath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K120958

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Office of Device Evaluation (ODE)

David Krause for MM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120958